

## **RESPONSE**

The Applicant wishes to thank the Examiner and his Supervisor for the telephone interview of August 27, 2008, with the inventor Jonathan B. Hall and the attorney of record, Mark F. Smith. The interview discussed reference U.S. Patent Application Publication of Godbey et al. (2002/0187181) and reference U.S. Patent Application Publication of Dole et al. (2003/0044366) with regard to Claims 1 and 7 of the subject application. No agreement was reached other than proposed claim language that the Examiner indicated might overcome concerns with respect to the two references. The Applicant agreed to provide a formal response to the outstanding Office Action.

Claims 1 and 7 - 25 remain in this application. Claim 1 has been withdrawn. Claims 1 and 12 have been objected to and Claims 7 – 25 have been rejected. Claims 1 and 7 have been amended to make the subject matter which the Applicants regard as the invention more clear. Support for the amendment can be found from the drawings, page 11, lines 11 – 17 and elsewhere in the Specification. The Applicants submit the following remarks and hereby requests a timely notice of allowance.

**The objection of Claims 1 and 12 is respectfully traversed.**

The Examiner has objected to Claims 1 and 12 because with regard to withdrawn Claim 1, which recites “an epidermal surfactant that has been applied.”

Withdrawn Claim 1 has been amended to overcome the Examiner's objection.

With respect to Claim 12, the Examiner has identified that the addition of the words "is" and "comprising" added in the last Response should have been underlined. Accordingly, Claim 12 has been amended as to overcome the Examiner's objection.

In view of the foregoing, the Applicants submit that the objection of Claims 1 and 12 should be withdrawn.

**The Rejection of Claims 7 - 25 under 35 USC 112, First Paragraph, as failing to comply with the written description requirement is respectfully traversed.**

Claims 7 - 25 have been rejected as failing to comply with the written description. Specifically, the Examiner takes the position that independent Claim 7 recites "a substrate having an image applied to the surface of the substrate" and "a surfactant placed along said surface of said substrate." The Examiner takes the position that the newly-added limitations are not supported by the Specification.

The Applicants respectfully submit that the Specification provides:

More particularly, in a preferred embodiment of the invention, the method comprises the steps of placing an image to the surface of a substrate and depositing a surfactant on a defined area along the surface of the

substrate, wherein the image operates to indicate the quantity or the continuing effectiveness of the surfactant. (Page 2, lines 18 – 22)

Further, the Specification provides:

The substrate 102 is further provided with an image 106 which is applied to the surface of the substrate 102 and may be formed from a dissolvable pigment, a decal or coating 107 (FIG. 4) effective for indicating the d that the image 106 and surfactant 104 may be placed at a single location along the substrate 102 and may cover the entire surface of the substrate 102 or may be placed at a plurality of selected locations thereof (FIG. 5). (Page 9, lines 21 – 24 and page 10, line 1)

Accordingly, the new limitations incorporated in independent Claim 7 are supported in the Specification as shown in the examples above, and elsewhere in the Specification.

Claims 8 – 25 are rejected as being dependent of independent Claim 7. Accordingly, Claims 8 – 25 should now be allowable.

In view of the foregoing, the rejection of Claims 7 – 25 under 35 U.S.C. 112, first paragraph, should be withdrawn.

**The rejection of Claims 7 – 25 under 35 U.S.C. 112, Second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is respectfully traversed.**

The Examiner takes the position that Claim 7 recites "a surfactant placed along

said surface of said substrate” is unclear as to where exactly the surfactant is placed or positioned on the invention. Claim 7, as amended, is clear that the image and the surfactant are deposited onto the same surface of the substrate and covers at least a portion of the image. The Applicants further submit that the original and amended Claims when read in light of the subject specification are clear and particularly point out and distinctly claim the subject invention and the Applicants have fully and properly described the invention and is not required to unduly limit the claims of the invention.

The Examiner also takes the position that the statement “effective for indicating the effectiveness” is indefinite. Accordingly, Claim 7 has been amended to make the subject matter which the Applicants regard as their invention more clear. Further, the Applicants submit that Claim 7, when read in light of the subject specification is clear and particularly points out and distinctly claims the subject invention.

The rejection of Claims 8 – 25 is based on rejected base Claim 7 and should now be allowable.

In view of the foregoing, the rejection of Claims 7 – 25 under 35 U.S.C. 112, Second paragraph, should be withdrawn.

**The rejection of Claims 7 - 9, 11 - 21 and 23 as being rejected under 35**

**U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication of Godbey et al. (2002/0187181) is respectfully traversed.**

The Examiner takes the position that Godbey et al. teaches an article for applying and monitoring a surfactant/surface active agent that comprises a substrate (carrier), an image positioned on the surface of the substrate (part of the one or more surface active agents in the layer/portion), and a surfactant deposited on the substrate (the one or more active agents). Further, Godbey teaches that the active agent can be associated with the carrier or adhesive as a coating applied to a surface of the carrier or adhesive and that the article can be used for such treatments as delivery of pharmaceutical treatments like drugs, hormones, antimicrobial agents, as well as cosmetic treatments such as the delivery of hair or skin colorants and transfer of designs, masks, tattoos or appliqué. Thus, the Examiner takes the position that if an active agent can be incorporated into the article along with an image such as a design, mask, tattoo or appliqué, then the proper transfer of the image to the skin would result in the proper delivery of the active agent associated therein.

Further, the Examiner takes the position that Godbey et al. teaches that the surfactant is an epidermal surfactant and that the surfactant can consist of any of the surfactants taught in the instant application.

The Applicants respectfully submit that nowhere in Godbey is there a suggestion

or a teaching with regard to monitoring a surfactant. Further, the Examiner's belief that one or more of the surfactant active agents is an "image" such as the image of the subject application is unfounded. The "image" as described in the subject application is applied to the surface of the substrate and is effective for indicating the quantity or continuing effectiveness of the surfactant. In contrast, the Examiner takes the position that Godbey et al. teaches a substrate (the carrier) and an image positioned on the surface of the substrate (citing the Abstract, paragraphs [0001], [0004], [0005], [0007], [0008], [0019] and [0020] Claim 1 of Godbey et al.). The Applicant submits that a review of the Examiner's citations does not show an image or even a teaching or a suggestion of the desirability of an image effective for indicating the quantity or continuing effectiveness of the surfactant. The device disclosed in Godbey et al. may have a "decorative utility, for example, as temporary tattoos, masks or decorative appliques on the skin, toenails, fingernails or teeth, or by delivering hair color or skin color" (see [0021]) or a delivery means such as for forming a mask (see [0033], or for providing treatment to fingernails or toenails (see [0050]). This "image" such as a tattoo described in Godbey functions more like a surfactant itself rather than the image described in the subject application that functions to indicate the quantity or the continuing effectiveness of the surfactant. Thus the "image" of Godbey is structurally and functionally significantly different than an image effective for indicating the quantity or continuing effectiveness of the surfactant.

The Examiner states that “if one of the active agents is to be an image, and the other agent is a different type of agent/surfactant, it follows that as the surfactant either wears off of or is absorbed into, the skin of the user, then the image that is presented could very easily fade or become more visible, depending on the nature of the surfactant that is covering the image portion of the article.” The Examiner however, shows no such image or even a suggestion or teaching of the desirability of such an image in the cited reference and has not satisfied the requirements for saying that the claim limitations are inherent in the cited reference. Further, the only disclosure of such an image or a teaching or suggestion of the desirability of such an image comes from the subject specification. Indeed, the only image disclosed in the cited reference are for decorative utility such as tattoos, masks or appliques on the skin, toenails, fingernails or teeth, or by delivering hair color or skin color.” As previously stated, the Applicants find no images effective for indicating the quantity or effectiveness of the surfactant. With respect to the claims rejected as anticipated under 35 USC 102, the MPEP provides that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). The alleged prior art invention “must be shown in as complete detail as contained in the... claim.” MPEP 2131 (quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). As shown above, the Examiner has not demonstrated that each element of the rejected

claims is contained in the cited prior art. Nor, has the Examiner shown that such an image is inherent in the reference invention.

The Examiner also takes the position that Godbey teaches that the surfactants ("active agents") are any agent providing any treatment to a user of the article, and that active agents include topical pharmaceutical agents, systemic pharmaceutical agents and cosmetic agents. Further, the Examiner states that Godbey recites that the active agent can be associated with the carrier or the adhesive layer by incorporating an agent into or depositing an agent onto a carrier or an adhesive layer, or as a coating applied to the surface of the carrier of adhesive. Further, Godbey provides the treatment provided by the article/agent shall be any desired effect provided by an active agent to a user. The Examiner, with little support, takes the giant leap and asserts:

...it follows that the device (or, article) can have an active agent that is of a decorative nature associated with the carrier and an active agent that is a pharmaceutical agent associated with the adhesive, and that the article can enable the user to transfer the decorative agent to one's skin or to the skin of another and in doing so, the complete transfer of the image will also result in the effective transfer of the pharmaceutical agent to the same skin. Thus, by knowing that the treatment provided by the article results in the effective transfer of the image, the user can also know that any/all other agents have also been delivered, thereby providing an indication as to the effective delivery of those other agents as well.

**Again, the Examiner is making the assertion that a device can have an active agent that is of a decorative nature associated with the carrier and an active agent that is a pharmaceutical agent associated with the adhesive**

together with the other claim elements thereby making the subject invention obvious. Indeed, the only showing of such a device or article is the Applicants' own specification.

As previously argued, **Godbey does not teach, suggest or disclose an image effective for indicating the quantity or continued effectiveness of the surfactant, and the Examiner has never shown in the Godbey such an image.**

Claims 8 - 9, 11 - 21 and 24 that depend from amended Claim 7 are believed to be allowable for the reasons stated above.

In view of the foregoing, the rejection of Claims 7 – 9, 11 – 21 and 23 as being anticipated by U.S. Patent Application Publication of Godbey et al. should be withdrawn.

**The rejection of Claims 10 and 22 under 35 U.S.C. 103(a) as being unpatentable over Godbey et al. and further in view of either Applicants' admissions or U.S. Patent Application Publication of Dole et al. (2003/0044366) is respectfully traversed.**

The Examiner takes the position that Godbey et al. teaches that an image can comprise colorants, dyes and printing and that the Applicants admit that the inks

described in the subject application are well-known in the art. The Examiner also takes the position that Dole et al. is drawn to a composition that changes color and teaches that the colorant can cause a color change as a surfactant dissipates. The Examiner believes that since Godbey et al., Dole et al. and the instant application are all drawn to related fields of the invention, they all address the specific use of the same surfactants on the skin of the user, it would have been obvious to a person having ordinary skill in the art to use the inks, especially in a color-changing composition, that are claimed in the instant application.

Further, the Examiner takes the position that Dole teaches that different types of inks are known in the art and that it is also known that using these inks can result in color change that will occur as the ink is either exposed to or subject to prolonged exposure to the skin. Specifically, Dole discusses the color change in terms of the sufficient drying of the application containing these inks and that the color change can be used to signal that the application has been left on long enough to provide the desired properties that the application is meant to deliver to the skin. Accordingly, the Examiner again takes the position that Godbey teaches an article to provide treatment to the user and that treatment refers broadly to the desired effect provided by the active agent, thus taken with Dole, which recites that a color change in the ink can signal that the composition has dried sufficiently, teaches the claimed invention. This is simply not true.

Indeed the subject invention is an article effective for indicating the quantity or continuing effectiveness of the surfactant when applied to the user. Unlike the combination proposed by the Examiner of Godbey and Dole (whereby color change is caused by drying), the article of the subject application can operate for washing whereby the article is subjected to water thereby preventing drying. Therefore, the proposed combination suggested by the Examiner is functionally different than the subject application. Further, nowhere is the color changes discussed in Dole et al. in reference to indicating the quantity or continued effectiveness of the surfactant.

In establishing a prima facie case of obviousness, three criteria must be met:

- i. Some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; and
- ii. A reasonable expectation of success; and
- iii. The prior art reference (or references when combined) must teach or suggest all the claim limitations.

MPEP § 2143. The Examiner has not established a prima facie case of obviousness with respect to applicant's Claims 10 and 22.

The Applicants submit that as shown above Godbey et al. does not teach, suggest, or disclose an image effective for indicating the quantity or effectiveness of the surfactant and there is no showing that one skilled in the art would be motivated to combine the teachings of the Godbey et. al. and Dole et al. to arrive at the claimed invention. The Examiner has only presented an argument that if

one combines the references and selects the proper surfactants, provides an image, and constructs the apparatus along the lines of the subject application, one could create the claimed invention. However, the Examiner fails to show the motivation to combine the cited references and to select and structure the apparatus in such a way as to create the claimed invention. Even if all of the elements of the claim are disclosed in the cited references, the claimed invention taken as a whole cannot be said to be obvious without some reason given in the prior art as to why one of ordinary skill would have been prompted to combine the teachings of the references in such a way as to arrive at the claimed invention.

Claim 10 depends on Claim 7 which requires an image that effective for indicating the quantity or effectiveness of the surfactant. The only teaching of such an image comes from the Applicants' own specification. Therefore, the combination of references does not teach or suggest all the claim limitations of Applicants' Claim 10.

The cited references do not contain any suggestion or motivation, either in the references themselves or in the knowledge generally available to one skilled in the art, to combine and modify the reference **and the Examiner has not provided any showing of such motivation or teaching.** The Examiner simply states that "Godbey teaches that a single article can comprise one active agent or that the article can also comprise multiple active agents. Therefore, if one of

the active agents is to be an image, and the other agent is a different type of agent/surfactant, it follows that as the surfactant either wears off or is absorbed into, the skin of the user, then the image that is present could very easily fade or become more visible, depending on the nature if the surfactant that is covering the image portion of the article.” Again, the only image disclosed in Godbey et al. comprises an image to be applied, such as a surfactant to the skin of a person. **There is no teaching that an “image” would be or should be covered by a surfactant or applied such that it fades when a surfactant is used, or becomes more visible when a surfactant is used.** Accordingly, the “image” taught in Godbey et al. is structurally and functional different than the “image” taught in the subject application. Further, Dole et al. teaches a skin care composition such as a facial mask comprising paste, lotion, gel or cream that changes color to indicate that the composition has dried sufficiently. Thus, the color change taught by Dole et al. is operates in a manner completely different than the claimed invention and does not operate to indicate the quantity or effectiveness of the surfactant and is therefore structurally and functionally different than the claimed article.

Because neither reference contains any teaching, motivation or suggestion for creating an article having an image effective for indicating the quantity or the continued effectiveness of the surfactant there could be no reasonable expectation of success in combining the references to read all the limitations of Claims 10 and 22. Therefore, this element of the prima facie case of

obviousness has not been established with respect to Applicants' Claims 10 and 22.

In view of the foregoing, the rejection of Claims 10 and 22 under 35 U.S.C. 103(a) as being unpatentable over Godbey et al. and further in view of either Applicant's admissions or U.S. Patent Application Publication of Dole et al. (2003/0044366) should be withdrawn.

In view of the foregoing Amendment and Remarks, Applicants respectfully request reconsideration of the Application and that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mark F. Smith", written in a cursive style.

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